EXHIBIT 1

IN THE CIRCUIT COURT OF THE THIRD JUDICIAL CIRCUIT MADISON COUNTY, ILLINOIS

ABIGAIL GROSSHUESCH, individually and as)			
Next Friend and Administrator of the Estate of)			
ISABELLA ZORMELO, Deceased)			
)			
Plaintiff,)			
)			
VS.)	No.	2021 L 00	01259
)			
MEAD JOHNSON & COMPANY, LLC; and)			
MEAD JOHNSON NUTRITION COMPANY,)			
)			
Defendants.))			

SUMMONS

To each defendant:

Mead Johnson & Company, LLC

Registered Agent: Illinois Corporation Service

801 Adlai Stevenson Drive Springfield, IL 62703

YOU ARE SUMMONED and required to file an answer to the complaint in this case, a copy of which is hereto attached, or otherwise file your appearance and pay the required fee within thirty (30) days after service of this Summons, not counting the day of service. To file your answer or appearance you need access to the internet. Please visit www.cookcountyclerkofcourt.org to initiate this process. Kiosks with internet access are available at all Clerk's Office locations. Please refer to the last page of this document for location information. If you fail to do so, a judgment by default may be entered against you for the relief requested in the Complaint.

To the officer: This summons must be returned by the officer or other person to whom it was given for service, with endorsement of service and fees, if any, immediately after service. If service cannot be made, this Summons shall be returned so endorsed. This Summons may not be served later than thirty (30) days after its date.

E-filing is not mandatory for document sin civil cases with limited exceptions. To e-file, you must first create an account with an e-filing service provider. Visit https://efile.illinoiscourts.gov/service-providers.htm to learn more and to select a service provider. If you need additional help or have trouble e-filing, visit http://www.illinoiscourts.cov/FAQ/gethelp.asp, or talk with your local circuit clerk's office.

Elizabeth A. Kaveny, ARDC #6211280 KAVENY + KROLL, LLC 130 E. Randolph St., Suite 2800 Chicago, IL 60601 312.761.5585

E-service: angelina@kavenykroll.com

10/20/2021
WITNESS:

/s/ Thomas McRae /s/ Jennifer Schaefer

Clerk of the Court

Date of Service:
(To be inserted by officer on copy
Left with defendant or other person)

Case 3:21-cv-01461 Document 1-1 Filed 11/19/21 Page 3 of 44 Page ID #9

Case Number 2021L 001259
Date: 10/18/2021 4:28 PM
Thomas McRae
Clerk of Circuit Court
Third Judicial Circuit, Madison County Illinois

IN THE CIRCUIT COURT OF THE THIRD JUDICIAL CIRCUIT MADISON COUNTY, ILLINOIS

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COMPLAINT

NOW COMES, Abigail Grosshuesch, Individually and as Next Friend and Administrator of the Estate of Isabella Zormelo. Deceased, by and through her attorneys, Levin, Rojas, Camassar, and Reck, LLC and KAVENY+KROLL, LLC, brings this Complaint and Demand for Jury Trial (the "Complaint") against Mead Johnson & Company, LLC and Mead Johnson Nutrition Company (together "Mead"). Plaintiff alleges as follows:

NATURE OF THE ACTION

- 1. This action arises out of the injuries suffered by Isabella Zormelo when, as a preterm infant, she was fed Mead's cow's milk-based infant formula product. Mead's product caused Isabella Zormelo to develop **Necrotizing Enterocolitis** ("**NEC**"), a devastating and often lethal disease that largely affects preterm babies who are given cow's milk-based formula products. As a result of being fed Mead's products, Isabella Zormelo died.
- 2. Plaintiff Abigail Grosshuesch brings this cause of action against Mead to recover for injuries that are the direct and proximate result of her child's consumption of Mead's unreasonably dangerous cow's milk-based infant formula products.

PARTIES

- 3. Abigail Grosshuesch is a resident of Florida and the mother of Isabella Zormelo ("Baby Isabella"). Abigail Grosshuesch is the Next Friend and Administrator of the Estate of Isabella Zormelo.
- 4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is in Illinois.
- 5. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company.
- 6. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, are manufacturers of cow's milk-based infant formula products and market many of its products under the "Enfamil" brand name.
- 7. Mead is the manufacturer of the infant formula product, Enfamil Acidified Liquid Human Milk Fortifier.

JURISDICTION AND VENUE

- 8. This Court has general jurisdiction over this action because Mead maintains its principal place of business in Illinois. 735 Ill. Comp. Stat. Ann. 5/2-209; see also Rios v. Bayer Corp., 2020 IL 125020, ¶ 19 (June 4, 2020) (citing Daimler AG v. Bauman, 571 U.S. 117, 137 (2014)).
- 9. Venue is proper in Madison County because Mead conducts business there. 735 ILCS 5/2-101; 735 ILCS 5/2-102(a).

FACTUAL ALLEGATIONS

Baby Isabella's NEC Diagnosis

- 10. Baby Isabella was born at Edward Hospital in Naperville, Illinois on October 13, 2013.
- 11. Baby Isabella was born preterm at 30 weeks, 2 days gestation age, weighing 1500 grams, just over 3 pounds.
- 12. Baby Isabella was described as a vigorous infant at birth. Her APGAR scores were 8 at one minute and 9 at five minutes.
- 13. From October 19, 2013 to October 23, 2013, Baby Isabella did well on her mother's breast milk, with a healthy and normal brain, progressing medically.
- 14. Starting in the afternoon on October 23, 2013, Baby Isabella was fed **Enfamil Acidified Liquid Human Milk Fortifier** ("Enfamil Liquid HMF"), a cow's milk-based product.
- 15. In the morning of October 27, 2013, after multiple small emeses, Baby Isabella was made NPO for suspected HMF intolerance.
 - 16. The next day, feeds of unfortified breast milk were restarted in the afternoon.
- 17. In the evening of October 28, 2013, Baby Isabella's feeds were fortified again with Enfamil Liquid HMF.
 - 18. After being fed the cow's milk-based product, Baby Isabella developed NEC.
- 19. On October 30, 2013, Baby Isabella had a bloody stool and was diagnosed with Necrotizing Enterocolitis.
- 20. In the early morning of October 31, 2013, Baby Isabella was forced to undergo an emergency exploratory surgery.
- 21. During that emergency exploratory surgery on October 31, 2013, it was discovered that Baby Isabella's intestines had extensively necrotized, requiring the resection of 100 cm of

ischemic, necrotic dead small intestine. Her abdomen was then temporarily closed in anticipation for a "second look" surgery.

- 22. After several hours of aggressive medical intervention, Baby Isabella's parents made the compassionate decision to withdraw life-saving measures.
- 23. On November 1, 2013 at 12:20 pm, Baby Isabella died in her mother's arms due to Necrotizing Enterocolitis.

Cow's Milk-Based Feeding Products Are Known to Cause NEC

- 24. NEC is the most frequent and most lethal gastrointestinal disorder affecting preterm infants.
- 25. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die.
- 26. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis.
 - 27. Up to 30 percent of NEC-diagnosed infants die from NEC.
- 28. Preterm and low birth weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based formula products significantly increase the incidence of NEC in preterm and low birth weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.
- 29. For example, in one randomized, multicenter study of 926 preterm infants, NEC was *six to ten* times more common in exclusively cow's milk formula-fed babies than in exclusively human breast milk-fed babies and *three times* more common in babies who received

a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was *20 times more common* in those only fed cow's milk formula than in those fed human milk.¹

- 30. Another randomized controlled trial showed that preterm babies fed an exclusive human milk-based diet were *90% less likely* to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.²
- 31. Another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a human milk-based fortifier.³
- 32. A Surgeon General report⁴ warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis," and states that premature infants who are not breastfed are *138% more likely* to develop NEC.
- 33. In 2012, the American Academy of Pediatrics ("AAP") issued a policy statement that *all* preterm infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized human donor milk.
- 34. This AAP recommendation was based on the "potent benefits of human milk," including "lower rates of . . . NEC."⁵

¹ Lucas A, Cole T. Breast milk and neonatal necrotising enterocolitis. Lancet 1990; 336: 1519–1523.

² Sullivan, S., et al, An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotising Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products. (Journal of Pediatrics 2010; 156:562-7).

³ Lucas, A. et al, *Preterm Infants fed Cow's Milk-Derived Fortifier Had Adverse Outcomes Despite a Base Diet of Only Mother's Own Milk.* (Breastfeeding Medicine 2020; 15 (5): 297-303.)

⁴ The Surgeon General's Call to Action to Support Breastfeeding.

⁵ Pediatrics 2012; 129:e827-e841, *Breastfeeding and the Use of Human Milk*.

- 35. A multicenter, randomized, controlled trial found that preterm and low birth weight infants fed an exclusive human milk-based diet suffered NEC only 3% of the time, while preterm and low birth weight infants receiving cow's milk-based formula suffered NEC 21% of the time.⁶
- 36. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of human milk fortified with a human milk-based fortifier or (b) a diet containing variable amounts of cow's milk-based products. The babies given exclusively human milk-based products suffered NEC 5% of the time. The babies given cow's milk-based products suffered NEC 17% of the time.

Safer, Nutritionally Superior Alternatives to Cow's Milk-Based Products Exist

- 37. A diet based exclusively on human milk and human milk-based products provides all the nutrition necessary to support preterm and low birth weight infants without the elevated risk of NEC associated with cow's milk-based products.
- 38. In a study analyzing preterm infants who were fed an exclusive human milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet. This is particularly true given the ability of human milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of an exclusive human milk diet.

⁶ Cristofalo, E.A., et al, Randomized trial of *Exclusive Human Milk versus Preterm formula*. (J Pediatr 2013 Dec; 163(6): 1592-1595).

⁷ Abrams, Steven, et al. *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products.* (Breastfeeding Medicine. 2014, Nov. 4, 9(6):281-286).

⁸ Hair, A, et al, BMC Research Notes 2013, 6:459, *Human milk feeding supports adequate growth in infants and HC gain birth weight.*

- 39. Mead's products not only pose a threat to infants' health, but also displace the human milk the infant could otherwise receive.
- 40. This displacement only increases infants' vulnerability to NEC, as studies show that human milk protects against the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive human milk-based diet is associated with significant benefits for extremely preterm infants and that it produced no feeding-related adverse outcomes.⁹
- 41. For the above reasons, experts acknowledge that human milk is the best source of nutrition for preterm infants and those at risk for NEC.
- 42. Exclusive human milk-based nutrition provides adequate nutrition for preterm infants while creating a significantly lower risk of NEC.
- 43. A range of options are available that allow preterm and low birth weight infants to be fed exclusively human milk-based nutrition. In addition to the mother's own breast milk, an established network delivers pasteurized donor breast milk to hospitals nationwide.
- 44. Moreover, hospitals have access to shelf-stable formula and milk fortifiers derived from pasteurized human breast milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.
- 45. At the time baby Isabella was fed Mead's cow's milk-based product, the science clearly demonstrated to Mead that the product caused and/or significantly increased the likelihood that a preterm baby will develop NEC, leading to devastating injury and often death.

⁹ Hair, et al, Breastfeeding Medicine 2016, 11-2, Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet.

- 46. Upon information and belief, Mead was aware of the significantly increased risk of NEC, devastating injuries, and/or death associated with its cow's milk-based products, and instead of warning of the dangers, providing instructions for safe use, conducting a scientifically-based risk-benefit analysis, or removing the products from market altogether, Mead has continued to use cow's milk as the foundation of its products.
 - 47. Mead's cow's milk-based products are unreasonably unsafe for preterm infants.
- 48. Alternatives existed in that Mead could have used pasteurized human breast milk instead of cow's milk for at-risk infants, which would have been safer.
- 49. Mead has made no changes to its products or the products' packaging, guidelines, instructions, or warnings.
- 50. Mead has instead continued to sell its unreasonably dangerous products to unsuspecting parents and healthcare providers.

False and Misleading Marketing Regarding Cow's Milk Based Infant Products

- 51. Notwithstanding strong medical evidence establishing the extreme dangers that cow's milk-based products pose for preterm infants, Mead has marketed its cow's milk-based products as equally safe alternatives to human milk and has promoted its products as necessary for additional nutrition and growth.
- 52. Mead has aggressively marketed its Enfamil cow's milk-based products as both medically endorsed and as a nutritionally equivalent alternative to human milk, including prior to Baby Isabella's birth.
- 53. Mead's marketing targets the parents of preterm infants while they are still in the hospital with messaging that Enfamil cow's milk formulas and fortifiers are necessary for the growth and development of its vulnerable children.

- 54. These tactics often implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk.¹⁰
- 55. None of Mead's marketing materials, including its promotional websites, reference the science showing how significantly its products increase the risk of NEC, devastating injuries, and/or death.
- 56. Aware of the impact of its advertising, Mead is willing to spend massive sums to disseminate this message.¹¹
- 57. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect of introducing partial bottle-feeding on breastfeeding, and the difficulty of reversing the decision not to breastfeed.
- 58. The Code also forbade advertising or other forms of promotion of formula to the general public, including providing sample products to mothers or members of its families.
- 59. While Mead acknowledges the Code on its websites and claims to support the effort to encourage mothers to breastfeed for as long as possible, Mead's aggressive marketing exploits new parents' darkest fears—that breast milk alone will not provide their baby with the very best chance of survival—while wholly failing to warn that its products come with a significantly increased risk of NEC, devastating injuries, and/or death.

Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

¹¹ One study estimates that formula manufacturers collectively spent \$4.48 billion on marketing and promotion in 2014 alone. *Baker, P, et al, Global trends and patterns of commercial milk-based formula sales: is an unprecedented infant and young child feeding transition underway? Public Health Nutrition, 2016.*

- 60. Recognizing that some countries have adopted the Code as law, a page of Mead's website entitled "Terms of Use" states: "Information for Non-U.S. Internet Users...Mead Johnson Nutrition endorses the aim of the World Health Organization (WHO) International Code of Marketing of Breast-milk Substitutes in developing countries, including standards for product integrity, labeling, distribution, and promotion."
- 61. Mead quotes from The Code that "breastfeeding is best for infants," but then contradicts the WHO by stating that "[f]ormula, when used properly, provides a sound nutritious substitute or supplement to breast milk, but it is more expensive."
- 62. Mead has long used its relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk, offering free formula, coupons, and even entire gift baskets to parents in hospitals, medical clinics, and residential charities where out-oftown families stay while its babies receive long-term treatment in the NICU.
- 72. Through this early targeting, Mead creates brand loyalty under the guise of a "medical blessing," in hopes that new parents will continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for Mead.
- 73. Consequently, these gift baskets have been shown to negatively impact breastfeeding rates.
- 74. Recognizing a shift in the medical community towards an exclusive human milk-based diet for premature infants, Mead developed a product called "Human Milk Fortifier," specifically designed for premature infants to be added to breast milk.
 - 75. This name is very misleading in that it suggests that the product itself is derived

from human milk when, in fact, it is a cow's milk-based product. 12

- 76. Mead has designed a powerful misleading marketing campaign to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider their brand's cow's milk-based products a first choice.
- 77. This marketing scheme is employed despite Mead knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants.
- 78. Mead's pervasive marketing over decades has caused parents in general, and Abigail Grosshuesch in particular, as well as hospitals, doctors, nurses, and medical staff to believe that Enfamil is safe for premature infants.
- 79. Abigail Grosshuesch was not instructed or informed that Enfamil can significantly increase the risk of her preterm baby getting NEC and dying.
- 80. This false belief that the products are safe, nutritious, and backed by science caused the cow's milk-based products to be fed to Isabella Zormelo.

Mead's Misleading Marketing of Enfamil

- 81. Mead has promoted its products for extremely premature infants and claims that Enfamil increases the babies' weight and caloric intake and that its products are more beneficial than harmful.
- 82. The studies show the Mead products should not be sold for use in extremely premature infants, yet Mead continued to market and sell its products knowing they would be used on premature babies like Isabella Zormelo and knowing its products would significantly increase

¹² Canvasser, J., *et al.* Parent and Provider Perspectives on the Imprecise Label of "Human Milk Fortifier" in the NICU. *Nutrients* 2020, *12*, 720

the risk of NEC, devastating injuries, and death in those premature infants.

- 83. Mead promotes a range of products specifically for "premature and low weight" babies on its website.
- 84. Mead falsely boasts its commitment to science on its website and claims that "Enfamil is backed by decades of breast milk research and multiple clinical studies" and it claims that "to create our best formulas, we collaborated on some of the most extensive breast milk studies to date."
- 85. These representations that Enfamil is backed by science and equivalent to breast milk mislead parents by intentionally omitting the established fact that cow's milk-based products have been proven to significantly increase the risk of NEC, devastating injuries, and/or death in premature infants.
- 86. When comparing infant formula and breast milk, Mead does not recognize the potent benefits of breast milk or acknowledge the risk of feeding cow's milk-based products to premature infants.
- 87. On a webpage entitled, "Choosing to Formula Feed," Mead features a pediatricianmom who tells parents "the decision [to formula feed] is purely personal."
- 88. This statement ignores the Code, the American Academy of Pediatrics, and the numerous studies demonstrating the superiority of breast milk by creating a false equivalency between formula and breast milk.
- 89. Mead uses bright colors and drop-down menus for its website, while making seemingly innocuous statements such as, "[w]hen it comes to making important choices about your baby's nutrition, there is nothing like a recommendation from a trusted source. Whether it comes from your pediatrician, the hospital where your baby was born or another mom, using Enfamil

gives you the confidence you've made the best choice for your baby."

- 90. Mead's website does not disclose the danger posed by its products to premature infants.
- 91. Mead also pays for ads on Google and other search engines specifically targeted to searches involving preterm infants and designed to net them more profit share of this lucrative market.
- 92. Mead markets its Enfamil brand as being wholly dedicated to providing safe and effective nutrition for children across the globe, boasting "[w]e understand the significance of the trust placed in us by parents, and we offer them ongoing reassurance about the uncompromising and rigorous quality standards to which we hold each and every facility, production line, employee, and product."
- 93. This statement misleads parents into believing that Mead's products are safe and based on the latest science, when in fact, science has proven its cow's milk-based products significantly increase the risk of NEC, devastating injuries, and death in preterm infants.
- 94. Mead also targets the parents of premature infants by emphasizing the need for catch-up growth.
- 95. The webpage for Enfacare makes the statement, "[c]linically shown to promote catch-up growth similar to full-term breastfed infants" and the webpage for Enfamil premature formula says that it "helps babies with catch-up growth."
- 96. This emphasis on catch-up growth suggests to parents of premature infants that breast milk alone will not provide enough nourishment to support adequate growth in their children.

- 97. One advertisement for Enfamil formula encourages parents to ask their child's pediatrician to write a prescription for Enfamil Enfacare so that their insurance will help to cover the cost.
- 98. Advertisements like this undermine the doctor-patient relationship and reduce a parent's capacity to make informed decisions regarding their infant's care.
- 99. Abigail Grosshuesch was told by her daughter's neonatologist, Dr. Michael Fitzgerald, that Enfamil Liquid HMF would help her baby gain weight and height.
- 100. Dr. Fitzgerald told Abigail Grosshuesch that this brand of fortifier would not make her baby chubby like a "Gerber baby."
- 101. Dr. Fitzgerald told Abigail Grosshuesch that the product was so expensive because it was so good.
- 102. Dr. Fitzgerald, Baby Isabella's neonatologist, told Abigail Grosshuesch that he was a spokesperson for Mead Johnson and that he trusted the brand completely.
- 103. Mead has designed a systematic, powerful, and misleading marketing campaign to deceive mothers to believe that: (1) cow's milk-based formula and fortifiers are safe; (2) cow's milk-based products are equal, or even superior to breastmilk; and (3) physicians consider their cow's milk-based products a first choice.
- 104. Similarly, Mead has marketed its products for premature infants as necessary for "catch-up growth," and perfectly safe for premature infants, despite knowing of the extreme risks posed by cow's milk-based products relative to the deadly disease of NEC to premature infants.
- 105. Abigail Grosshuesch was exposed to and believed this deception which caused and/or substantially contributed to her baby being fed Mead's cow's milk-based product.

106. Abigail Grosshuesch, members of the medical community, physicians, and hospitals relied upon the representations and advertising of Mead, which categorically omit that its cow's milk-based products significantly increase the risk of NEC and death in premature infants, which substantially contributed to the products being fed to Isabella Zormelo.

Mead's Enfamil Human Milk Fortifier

- 107. Mead's Enfamil Acidified Liquid Human Milk Fortifier is a cow's milk-based product.
- 108. Cow's milk-based products significantly increase the risk that a preterm infant will develop NEC, devastating injuries, and/or death.
- 109. Mead's Enfamil cow's milk-based products are dangerous to preterm infants in that they significantly increase the risk that the baby will develop NEC.
- 110. Mead's Enfamil cow's milk-based products are dangerous to preterm infants in that they significantly increase the risk that the baby will die.
- 111. Despite knowing that its products significantly increase the risk of NEC, devastating injuries, and/or death, Mead deliberately chose to omit a specific warning of NEC, devastating injuries, and/or death, and deliberately failed to provide any detailed instructions and/or guidance on how to avoid NEC and/or death when feeding Enfamil to a preterm infant.
- 112. Mead failed to properly warn that its Enfamil cow's milk-based products can significantly increase the risk that a preterm infant will develop NEC, devastating injuries, and/or die, as occurred to Isabella Zormelo.
- 113. Mead's Enfamil cow's milk-based products did cause Baby Isabella to develop NEC, which caused Baby Isabella to become critically ill, undergo invasive surgery, and die.
 - 114. Prior to October 13, 2013, Mead was aware, or should have been aware, that its

product, Enfamil Liquid HMF, was not safe for use, as it was used in preterm infants like Baby

Isabella, yet it took no steps to prevent its use in such a situation.

Mead did foresee, or should have foreseen, that its Enfamil cow's milk-based 115.

products would be used as they were in the case of Baby Isabella and knew or should have known

that such use would significantly increase the risk of NEC in Baby Isabella, yet it took no steps to

prevent such use.

Mead's Enfamil cow's milk-based product was not safe to be used as it was in the 116.

case of Baby Isabella, and Mead knew or should have known it was unsafe, yet it failed to properly

instruct and/or warn the FDA, NICUs, hospitals, doctors and parents that its product was not safe.

Mead's Enfamil cow's milk-based product was not safe to be used as it was in the 117.

cases of Baby Isabella, and Mead knew or should have known it was unsafe, yet it failed to provide

detailed instructions or guidelines on when and how its product would be safe to use in preterm

infants like Baby Isabella.

Mead's Inadequate Warnings

Mead's aggressive marketing campaign is designed to make parents believe that its 118.

products are safe and necessary for the growth of premature infants, despite decades of research

that establish the fact that cow's milk-based products significantly increase the risk of a premature

infant developing NEC, devastating injuries, and/or death.

119. The product Enfamil Acidified Liquid Human Milk Fortifier, which Mead markets

specifically as being safe and necessary for premature infants, is available at retail locations and

online. No prescription is necessary.

Mead's product, Enfamil Acidified Liquid Human Milk Fortifier, contains only the 120.

following packaging information, warnings, and instructions:

WARNING: Your baby's health depends on carefully following the instructions below.

Use only as directed by a medical professional. Improper hygiene, preparation, dilution, use or storage may result in severe harm. Although this powder is formulated for premature infants, nutritional powders are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor.

Follow hospital rules or your baby's doctor's instructions for the safe handling of human milk.

To aid mixing, agitate the human milk well. Pour the desired amount into a sterile container and warm to feeding temperature.

- 1. Remove vials from foil pouch and separate number of vials needed.
- 2. Store remaining vials in foil pouch at room temperature. Once pouch has been opened, vials must be used within 24 hours.
- 3. Shake vigorously to mix contents. Firmly hold vial UPRIGHT by bottom tab and slowly twist top off completely. Add fortifier to breast milk.

Some liquid may remain in cap and vial; disregard [sic] this liquid. Discard opened vial and cap promptly. Do not use product that has unusual characteristics.

- 1. Failure to follow these instructions could result in severe harm. Once prepared, fortified breast milk can spoil quickly. Either feed fortified breast milk immediately or cover and store in refrigerator at 35-40°F (2-4°C) for no longer than 24 hours. Agitate before each use.
- 2. **For bottle feeding:** Pour only the amount of fortified breast milk to be fed into a feeding container and feed immediately. Do not use fortified breast milk if it is unrefrigerated for more than a total of 2 hours. After feeding begins, use fortified breast milk within one hour or discard.
- 3. **For tube feeding:** Once fortified breast milk is prepared, it can remain at room temperature for no longer than a total of 4 hours.

Warning: Do not use a microwave oven to warm the fortified human milk. Serious burns may result.

Storage: Store unopen pouches in carton at room temperature. Avoid excessive heat. Do not freeze.

Warning: Not for parental (I.V.) use. Fortifier is designed to be mixed with breast milk; do not administer directly.

121. Despite knowing of the increased risk of NEC, devastating injuries, and/or death, Mead did not warn of the significantly increased risk of NEC, devastating injuries, and/or death associated with Enfamil Acidified Liquid Human Milk Fortifier, nor of the magnitude of this increased risk.

- 122. Mead likewise did not provide instructions or guidance for how to feed these products in order to avoid NEC, devastating injuries, and/or death.
- 123. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil Acidified Liquid Human Milk Fortifier is a safe and necessary alternative, supplement and/or substitute to breast milk.
- 124. Despite knowing that its products were being fed to preterm infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals or hospitals inform parents of the significant risk of NEC, devastating injuries, and/or death.
- 125. Despite knowing that its products were being fed to preterm infants, often without the parents' informed consent, Mead failed to require or recommend that parental consent be obtained prior to the products being fed to their babies.

The Practice of Silence by Mead: No Warnings, No Instructions, and No Information Provided to the Parents

- 126. Despite learning that its Enfamil products were linked to NEC, devastating injuries, and/or death, Mead failed to properly collect data from patients, parents, doctors, and hospitals in order to develop evidence-based strategies, instructions, and warnings to reduce or prevent its products from causing NEC, devastating injuries, and/or death.
- 127. Despite knowing its Enfamil products were causing NEC, devastating injuries, and/or death, Mead took no steps to determine how or why its products were causing NEC, devastating injuries, and/or death, and did not conduct comprehensive risk management plans to combat the tragic end results of using its products.
- 128. Mead has learned that its cow's milk-based Enfamil products were causing NEC, devastating injuries, and/or death in preterm infants, yet they did nothing to change its products, packaging, guidelines, instructions, and warnings.

- 129. Despite knowing that its cow's milk-based Enfamil products were causing NEC, devastating injuries, and/or death in preterm infants, Mead did not conduct any testing, data analysis, or research to determine when its products should not be used or when and how its products were safe for use.
- 130. Despite knowing that its products were causing NEC, devastating injuries, and/or death in preterm infants, Mead did not contact the FDA to inform them that its products were linked to NEC, devastating injuries, and/or death.
 - 131. Abigail Grosshuesch was aware Mead's product was being fed to her baby.
- 132. None of the products at issue warned of any risk of NEC, devastating injuries, and/or death.
- 133. Abigail Grosshuesch was never told that the product could cause and/or increase the risk of her baby developing NEC.
- 134. Abigail Grosshuesch was never told that the product could cause and/or increase the chance her baby will die.
- 135. Abigail Grosshuesch was never told of the studies showing cow's milk-based formula was extremely dangerous to her baby.
- 136. Abigail Grosshuesch was never told of the studies showing that mother's own breast milk and human donor milk were safer for her baby.
- 137. Abigail Grosshuesch did not question the safety of the products because the brand name "Enfamil" in general, and the product at issue, are marketed as safe and healthy and similar to breast milk and are regularly sold in stores and/or used in hospitals.
- 138. The general public, including Abigail Grosshuesch, believe Enfamil is safe because Mead has protected its formula brand by deceptively misleading the public and deliberately hiding

the fact that Enfamil has been scientifically linked to significantly increasing the risk of NEC, devastating injuries, and death in premature infants for decades.

- 139. Abigail Grosshuesch trusted the brand Enfamil and allowed the product to be fed to her baby.
- 140. Abigail Grosshuesch had been a strong advocate involved in her baby's care throughout her life.
- 141. Had Abigail Grosshuesch known of the significant risk of feeding Enfamil Acidified Liquid Human Milk Fortifier to a preterm infant, she would not have allowed the product to be fed.
- 142. Mead is aware that its Enfamil products do not warn of NEC, devastating injuries, and/or death and is aware that doctors and hospitals do not warn of NEC, devastating injuries, and/or death before feeding the products to preterm infants.
- 143. Mead has done nothing to inform parents of the increased risk of NEC, devastating injuries, and/or death to premature infants fed Enfamil.
- 144. This practice of silence furthers the false belief that Enfamil is safe and healthy for premature infants, and continues its significant usage throughout the United States, and places profits ahead of protecting premature infants and its parents.
 - 145. In no uncertain terms, Enfamil products should state this warning or similar:

WARNING: THIS PRODUCT CONTAINS COW'S MILK WHICH STUDIES SHOW SIGNIFICANTLY INCREASES THE RISK OF NECROTIZING ENTEROCOLITIS (NEC), LIFE-THREATENING INJURIES, AND/OR DEATH IN PREMATURE INFANTS WHEN COMPARED TO HUMAN MILK.

Before feeding this product to a premature infant, parent(s)/guardian(s) must be counselled regarding the potential risks and benefits of cow's milk-based formula, including the increased risk of necrotizing enterocolitis (NEC), life-threatening

injury, and/or death in premature infants, when compared to a human milk-based diet. NEC may result in bowel necrosis, requiring surgical removal of the necrotic tissue. NEC is associated with high infant mortality. Parent(s)/guardian(s) should be informed that mother's milk (including human donor milk) or human milk-based formulas and fortifiers are associated with a significant reduction in the risk of NEC, life-threatening injury, and/or death. Before feeding this product, parent(s)/guardian(s) must be presented the option for human milk-based feedings. All attempts should be made to obtain parent(s)/guardian(s) consent prior to using this product.

- 146. Mead has known that its Enfamil products are significantly increasing the risk of NEC, devastating injuries, and/or death in preterm infants, and is aware that there are safer alternatives to its cow's milk-based formulas, such as human milk-based products, that would reduce the risk of NEC, devastating injuries, and/or death, yet Mead chose to continue to promote, market, and sell its cow's milk-based products, with no warnings, safety measures, or alerts, which results in the Enfamil products continuing to be fed to preterm infants, causing thousands of babies to be exposed to an unnecessary risk, many of whom will suffer from NEC and/or die.
- 147. Abigail Grosshuesch never knew, nor should Abigail Grosshuesch have reasonably known, that Mead's cow's milk-based food products could cause NEC and/or death.
- 148. In order to profit from its cow's milk-based products, Mead deliberately hid the extreme dangers of feeding these products to premature infants.
- 149. No parent would ever suspect a food product to be extremely dangerous to its baby unless they were properly warned and informed of the extreme dangers and risk of NEC and/or death.
- 150. Mead should be barred from arguing that the statute of limitations has run on unknowing parents whose babies where severely injured or died, until such time as Mead finally warns, informs, and instructs the public and the parents that its products significantly increase the risk of NEC and death when fed to premature infants.

151. To this day, Mead still does not admit nor warn that its products significantly increase the risk of NEC and death in premature infants.

COUNT I: STRICT LIABILITY - DESIGN DEFECT

- 1. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.
- 2. Mead, as the manufacturer and/or seller of the products at issue in this litigation, had a responsibility to manufacture, sell, and distribute its products in a manner that was not unreasonably dangerous.
- 3. Mead's product contained cow's milk at the time they left the manufacturing facility.
- 4. Mead knew or reasonably should have known that cow's milk-based nutrition is unreasonably dangerous as it carries a significantly increased risk of preterm infants developing NEC, serious injury, and/or death.
- 5. Mead knew or reasonably should have known that the risks involved in feeding a preterm infant cow's milk-based nutrition outweighed the benefits.
- 6. Mead knew or reasonably should have known that human milk-based nutrition did not carry the same risks of NEC, devastating injury, and/or death that its own cow's milk-based products do.
- 7. Mead knew or reasonably should have known that its cow's milk-based products would be used—unaltered—to feed preterm infants like Baby Isabella.
- 8. An ordinary consumer would not expect Mead's cow's milk-based products to carry a significant risk of devastating injury and death from NEC.

- 9. Mead did not develop a human milk-based product that was safer for premature infants and did not reformulate its products to reduce the risk of NEC, devastating injury, and/or death, even though doing so was economically feasible and even though pasteurized human milk was an available alternative.
- 10. Mead's cow's milk-based product, Enfamil Acidified Liquid Human Milk Fortifier was in fact fed—unaltered—to Baby Isabella.
- 11. As a direct result of Baby Isabella's ingesting of the Enfamil cow's milk-based product, she developed surgical NEC which resulted in the loss of portions of her intestine and her death.
- 12. The aforesaid negligent acts and/or omissions of Mead proximately caused Baby Isabella to develop NEC, which caused her death on November 1, 2013.
- 13. As a direct and proximate result of the aforesaid negligent acts and/or omissions, Mead proximately caused Baby Isabella's next of kin to suffer damages, including but not limited to, loss of money, benefits, goods, services, society, grief, sorrow, and mental suffering resulting from her death.
- 14. This count is brought pursuant to the Illinois Survival Act, 755 ILCS 5/27-6, the Illinois Family Expense Act, 750 ILCS 65/15, and the Illinois Wrongful Death Act, 740 ILCS 180/1.

WHEREFORE, Abigail Grosshuesch, Individually, and as Next Friend and Administrator of the Estate of Isabella Zormelo, Deceased, demands judgment against Mead Johnson & Company, LLC and Mead Johnson Nutrition Company, for a sum in excess of the jurisdictional limits of the Circuit Court of Madison County, Illinois.

COUNT II: STRICT LIABILITY – DESIGN DEFECT – LOSS OF CONSORTIUM

Abigail Grosshuesch v. Mead Johnson & Co., LLC & Mead Johnson Nutrition Co.

- 15. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
 - 16. At all times relevant herein, Abigail Grosshuesch was Isabella Zormello's mother.
- 17. Abigail Grosshuesch, as Isabella Zormello's mother, has suffered injuries including, but not limited to, loss of consortium.

WHEREFORE, Abigail Grosshuesch, Individually, demands judgment against Mead Johnson & Co., LLC & Mead Johnson Nutrition Company, LLC for a sum in excess of the jurisdictional limits of the Circuit Court of Madison County, Illinois.

COUNT III: STRICT LIABILITY FOR FAILURE TO WARN

- 18. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.
- 19. Mead, as the manufacturer and/or seller of the infant product at issue in this litigation, was required to provide adequate warnings or instructions about the dangers and risks associated with the use of its product with preterm infants, specifically including, but not limited to, the risk of NEC, devastating injury, and/or death.
- 20. By designing its product with cow's milk-based ingredients, Mead was required to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, devastating injury, and/or death.
- 21. Mead's product contained cow's milk at the time they left the manufacturing facility.

- 22. Mead's failure to warn of the unreasonable risk of harm posed by the ingredients of its product makes the product at issue in this litigation unreasonably dangerous.
- 23. Mead knew or should have known that cow's milk-based nutrition was unreasonably dangerous as it carried a significantly increased risk of premature infants developing NEC, devastating injuries, and/or death.
- 24. Mead knew or should have known that the risks involved in feeding a premature infant cow's milk-based nutrition outweighed the benefits.
- 25. An ordinarily consumer would not expect Mead's cow's milk-based products to carry a significant risk of devastating injury and death from NEC.
- 26. Mead knew or should have known that its cow's milk-based premature infant products would be fed—unaltered—to premature infants like Baby Isabella.
- 27. Mead knew or should have known that human milk-based nutrition did not carry the same risks of NEC, devastating injury, and/or death that its own cow's milk-based products do.
- 28. Mead knew or should have known that its cow's milk-based product might cause those premature infants to develop NEC, devastating injury, and/or death, yet it failed to provide adequate warnings of those risks. Among other risks, Mead:
 - a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, devastating injury, and/or death in those babies;
 - b. Failed to warn that cow's milk-based products are unsafe and/or contra-indicated for preterm infants like Baby Isabella;
 - c. Carried warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC, devastating injuries, and death;

- d. Failed to carry a large and prominent "black box" type warning that its cow's milk-based products are known to significantly increase the risk of NEC, devastating injuries, and/or death when compared to breast milk in preterm infants;
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC, devastating injuries, and/or death in preterm infants;
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Enfamil, notwithstanding their substantial risks;
- g. Failed to provide a warning in a method reasonably calculated and/or expected to reach the baby's parents;
- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in preterm infants associated with cow's milk-based products;
- i. Failed to properly warn hospitals, NICUs, doctors, parents and/or consumers that its cow's milk-based products significantly increase the risk of NEC, devastating injuries, and/or death in these babies;
- j. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed Enfamil to preterm infants in order to decrease the risk of NEC, devastating injuries, and/or death;
- k. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of its product;
- 1. Failed to otherwise warn physicians and healthcare providers of the extreme risk associated with feeding preterm infants cow's milk-based formula;
- m. Failed to send out "Dear Dr." letters warning of the risks of NEC, devastating injuries, and/or death and the current scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;
- Failed to instruct or warn that an exclusive human milk-based diet significantly decreases the risk of NEC, devastating injuries, and/or death when compared to a diet containing cow's milk;
- o. Failed to require or recommend hospitals and/or physicians inform parents that Enfamil significantly increases the risk of NEC, devastating injuries, and/or death before allowing the product to be fed to their preterm infants;
- p. Failed to provide a thorough and detailed risk-benefit analysis for hospitals, doctors, and parents;

- q. Failed to develop comprehensive mitigation strategies to reduce the risk of NEC, devastating injuries, and/or death in its products;
- r. Failed to establish a label or instruction that would correspond to the current science regarding the positive risk-benefit profile; and/or
- s. Failed to provide statistical evidence of adverse effects regarding the feeding of its products.
- 29. Had physicians and healthcare providers known of the extreme risk associated with feeding premature infants cow's milk-based fortifier, they would not have fed Baby Isabella those products.
- 30. Had Baby Isabella's mother known of the significant risks of feeding Baby Isabella cow's milk-based products, she would not have allowed such products to be fed to her child.
- 31. Had Baby Isabella's mother known of the significant risks of feeding Baby Isabella cow's milk-based products, she would not have fed such products to her child.
- 32. As a direct result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of its products, Baby Isabella was fed Enfamil Acidified Liquid Human Milk Fortifier, Mead's cow's milk-based product.
- 33. The aforesaid negligent acts and/or omissions of Mead proximately caused Baby Isabella to develop NEC, which caused her death on November 1, 2013.
- 34. As a direct and proximate result of the aforesaid negligent acts and/or omissions, Mead proximately caused Baby Isabella's next of kin to suffer damages, including but not limited to, loss of money, benefits, goods, services, society, grief, sorrow, and mental suffering resulting from her death.

35. This count is brought pursuant to the Illinois Survival Act, 755 ILCS 5/27-6, the Illinois Family Expense Act, 750 ILCS 65/15, and the Illinois Wrongful Death Act, 740 ILCS 180/1.

WHEREFORE, Abigail Grosshuesch, Individually, and as Next Friend and Administrator of the Estate of Isabella Zormello, Deceased, demands judgment against Mead Johnson & Co., LLC & Mead Johnson Nutrition Co., for a sum in excess of the jurisdictional limits of the Circuit Court of Madison County, Illinois.

COUNT IV: STRICT LIABILITY FOR FAILURE TO WARN LOSS OF CONSORTIUM

Abigail Grosshuesch v. Mead Johnson & Co., LLC & Mead Johnson Nutrition Co.

- 36. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
 - 37. At all times relevant herein, Abigail Grosshuesch was Isabella Zormelo's mother.
- 38. Abigail Grosshuesch, as Isabella Zormelo's mother, has suffered injuries including, but not limited to, loss of consortium.

WHEREFORE, Abigail Grosshuesch, Individually, demands judgment against Mead Johnson & Co., LLC & Mead Johnson Nutrition Company, LLC for a sum in excess of the jurisdictional limits of the Circuit Court of Madison County, Illinois.

COUNT V: NEGLIGENCE

- 39. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.
- 40. Mead, as the manufacturer and/or seller of the products at issue in this litigation, owed a duty to exercise reasonable care to design, test, manufacture, inspect, and distribute a

product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

- 41. Mead, as the manufacturer and/or seller of the products at issue in this litigation, knowing for many years that its cow's milk-based products cause and/or significantly increase the risk of NEC, devastating injuries, and/or death in premature infants, had a duty to act as a reasonably prudent manufacturer to aggressively and promptly take significant actions to reduce the risks of its products causing NEC, devastating injuries, and/or death in premature infants.
- 42. At all times relevant to this action, Plaintiff, Baby Isabella, and her health care providers used the products at issue in their intended manner and for their intended purpose.
- 43. Mead negligently made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant formula products at issue in this litigation and thereby breached its duty to the general public and Plaintiffs.
- 44. Mead knew or reasonably should have known that its cow's milk-based infant products significantly increased the risk of NEC, devastating injuries, and/or death.
 - 45. Mead failed to act in a reasonably prudent manner and breached their duty by:
 - a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, devastating injuries, and death in those babies;
 - b. Failing to warn that cow's milk-based products are unsafe and/or contra-indicated for preterm infants like Baby Isabella;
 - c. Carrying warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC, devastating injuries, and/or death;
 - d. Failing to carry a large and prominent "black box" type warning that its cow's milk-based products are known to significantly increase the risk of NEC, devastating injuries, and/or death when compared to breast milk in preterm infants;

- e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC, devastating injuries, and/or death in preterm infants;
- f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Mead's products, notwithstanding their substantial risks;
- g. Failing to provide a warning in a method reasonably calculated/expected to reach the baby's parents;
- Failing to provide statistical evidence showing the magnitude of increased risk of NEC, devastating injuries, and/or death in preterm infants associated with cow's milk-based products;
- i. Failing to collect data to determine if its products were safe for preterm infants;
- j. Failing to collect data to determine when and how its products could be used safely;
- k. Failing to utilize the significant body of peer-reviewed research to develop instructions and/or warnings on how and when its products should be used in order to protect babies from NEC, devastating injuries, and/or death;
- 1. Continuing to utilize outdated and ineffective instructions and warnings knowing they were inadequate based in modern science;
- m. Failing to continuously and vigorously study its cow's milk-based products in order to avoid NEC, devastating injuries, and/or death in preterm infants;
- n. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC, devastating injuries, and/or death;
- o. Failing to develop a protocol for hospitals and physicians with the elements to assure safe use:
- p. Failing to establish a standard for safe use;
- q. Failing to properly and thoroughly identify the hazards associated with its products to minimize its risks to preterm infants;
- r. Failing to take reasonable steps to protect preterm infants from developing NEC, devastating injuries, and/or death when feeding Enfamil;
- s. Failing to properly work with physicians and hospitals to develop ways to reduce NEC, devastating injuries, and/or death when Enfamil was fed to preterm infants;

- t. Failing to market and/or sell its products in a way which would protect the preterm infants from NEC, devastating injuries, and/or death;
- u. Failing to provide proper training or information to health care providers for safe use of its products;
- v. Failing to take reasonable precautions to prevent preterm infants from developing NEC, devastating injuries, and/or death;
- w. Failing to properly or promptly notify the FDA that its cow's milk-based products were significantly increasing NEC, devastating injuries, and/or death in preterm infants;
- x. Despite knowing for many years that the most vulnerable humans were suffering extreme harm related to the feeding of its products, failing to properly perform a type of pharmacovigilance for the scientific process of collection, detection, assessment, monitoring, and prevention of adverse effects for its cow's milk-based formulas;
- y. Improperly creating agreements with hospitals whereby its products would be over utilized to the detriment of the preterm infants;
- z. Improperly promoting continued use of its products in hospitals despite knowing of the great harm they were causing;
- aa. Improperly providing free and/or reduced-price Enfamil products to hospitals which has caused significant harm to preterm infants across the United States;
- bb. Failing to establish a label or instruction that would correspond to the current science regarding the positive risk-benefit profile;
- cc. Failing to provide a thorough and detailed risk-benefit analysis for hospitals, doctors, and parents;
- dd. Failing to provide statistical evidence of adverse effects regarding the feeding of its product;
- ee. Failing to provide periodic or yearly safety reports;
- ff. Failing to provide periodic or yearly risk-benefit analysis for use of its products;
- gg. Failing to provide or produce yearly safety update reports;
- hh. Failing to develop comprehensive mitigation strategies to reduce the risk of NEC, devastating injuries, and/or death in its products; and/or

- ii. Intentionally promoting a culture of silence whereby the harmful effects of its products were never being communicated to the parents or the public.
- 46. The aforesaid negligent acts and/or omissions of Mead proximately caused Baby Isabella to develop NEC, which caused her death on November 1, 2013.
- 47. As a direct and proximate result of the aforesaid negligent acts and/or omissions, Mead proximately caused Baby Isabella's next of kin to suffer damages, including but not limited to, loss of money, benefits, goods, services, society, grief, sorrow, and mental suffering resulting from her death.
- 48. This count is brought pursuant to the Illinois Survival Act, 755 ILCS 5/27-6, the Illinois Family Expense Act, 750 ILCS 65/15, and the Illinois Wrongful Death Act, 740 ILCS 180/1.

WHEREFORE, Abigail Grosshuesch, Individually, and as Next Friend and Administrator of the Estate of Isabella Zormelo, Deceased, demands judgment against Mead Johnson & Co., LLC & Mead Johnson Nutrition Company, LLC, for a sum in excess of the jurisdictional limits of the Circuit Court of Madison County, Illinois.

COUNT VI: NEGLIGENCE – LOSS OF CONSORTIUM

- 49. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
 - 50. At all times relevant herein, Abigail Grosshuesch was Isabella Zormelo's mother.
- 51. Abigail Grosshuesch, as Isabella Zormelo's mother, has suffered injuries including, but not limited to, loss of consortium.

WHEREFORE, Abigail Grosshuesch, Individually, demands judgment against Mead Johnson & Co., LLC & Mead Johnson Nutrition Company, LLC for a sum in excess of the jurisdictional limits of the Circuit Court of Madison County, Illinois.

COUNT VII: INTENTIONAL MISREPRESENTATION

- 52. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.
- 53. At all times relevant to this action, Baby Isabella, by and through her physicians, medical professionals, medical staff, nurses, and her family, used the products at issue in their intended manner and for their intended purpose.
- 54. Mead, as the manufacturer and/or seller of the infant formula products at issue in this litigation, owed a duty to provide truthful and accurate information about the risks and benefits of using its product when used in the intended manner and for the intended purpose.
- 55. Mead breached its duty through misrepresentations made to consumers, physicians, and medical staff in its advertising and promotional materials, as described in previous paragraphs and incorporated herein.
- 56. Specifically, upon information and belief, Mead intentionally made the following false statements of material fact on an ongoing and repeated basis and prior to the time Baby Isabella was fed its products:
 - a. That its cow's milk-based products were safe and beneficial for preterm infants;
 - b. That its cow's milk-based products were necessary to the growth and nutrition of preterm infants;
 - c. That its products have no serious side effects;
 - d. That cow's milk-based products are safe for preterm infants;

- e. That cow's milk-based products are necessary for optimum growth;
- f. That cow's milk-based products are similar or equivalent to breast milk;
- g. That Enfamil was safe and more like breast milk than other infant products; and/or
- h. That its products were based on up-to-date science, which made them safe for preterm infants.
- 57. Mead knew or reasonably should have known those statements to be false.
- 58. Those misrepresentations were intended to, and in fact did, induce hospitals and health care providers, including Baby Isabella's hospital and health care providers, to provide Enfamil Acidified Liquid Human Milk Fortifier to babies, including Baby Isabella.
- 59. Mead's misrepresentations induced Abigail Grosshuesch to allow her child to be fed Mead's Enfamil Acidified Liquid Human Milk Fortifier, in reliance on all the messaging she received about formula feeding, including, directly or indirectly, Mead's messaging.
 - 60. As a direct result, Mead's products were fed to Baby Isabella.
- 61. Had Mead not committed these intentional misrepresentations, Baby Isabella would not have been exposed to its unreasonably dangerous cow's milk-based product.
- 62. The aforesaid acts and/or omissions of Mead proximately caused Baby Isabella's NEC and her death on November 1, 2013.
- 63. As a direct and proximate result of the aforesaid negligent acts and/or omissions, Mead proximately caused Baby Isabella's next of kin to suffer damages, including but not limited to, loss of money, benefits, goods, services, society, grief, sorrow, and mental suffering resulting from her death.
- 64. This count is brought pursuant to the Illinois Survival Act, 755 ILCS 5/27-6, the Illinois Family Expense Act, 750 ILCS 65/15, and the Illinois Wrongful Death Act, 740 ILCS 180/1.

WHEREFORE, Abigail Grosshuesch, Individually, and as Next Friend and Administrator of the Estate of Isabella Zormelo, Deceased, demands judgment against Mead Johnson & Co., LLC & Mead Johnson Nutrition Company, LLC, for a sum in excess of the jurisdictional limits of the Circuit Court of Madison County, Illinois.

COUNT VIII: INTENTIONAL MISREPRESENTATION – LOSS OF CONSORTIUM

Abigail Grosshuesch v. Mead Johnson & Co., LLC & Mead Johnson Nutrition Co.

- 65. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
 - 66. At all times relevant herein, Abigail Grosshuesch was Isabella Zormelo's mother.
- 67. Abigail Grosshuesch, as Isabella Zormelo's mother, has suffered injuries including, but not limited to, loss of consortium.

WHEREFORE, Abigail Grosshuesch, Individually, demands judgment against Mead Johnson & Co., LLC & Mead Johnson Nutrition Company, LLC for a sum in excess of the jurisdictional limits of the Circuit Court of Madison County, Illinois.

COUNT IX: NEGLIGENT MISREPRESENTATION

- 68. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.
- 69. At all times relevant to this action, Baby Isabella, by and through her physicians, medical professionals, medical staff, nurses, and her family, used the products at issue in their intended manner and for their intended purpose.
- 70. Mead, as the manufacturer and/or seller of the products at issue in this litigation, owed a duty to provide truthful, accurate, fulsome information about the risks and benefits of using its products when used in the intended manner and for the intended purpose.

- 71. Mead breached its duty through misrepresentations made to consumers, physicians, and medical staff in its advertising and promotional materials, as described in previous paragraphs and incorporated herein.
- 72. Specifically, upon information and belief, Mead negligently made the following false statements of material fact on an ongoing and repeated basis and prior to the time Baby Isabella was fed Enfamil:
 - a. That its cow's milk-based products were safe and beneficial for preterm infants;
 - b. That its cow's milk-based infant products were necessary to the growth and nutrition of preterm infants;
 - c. That its products have no serious side effects;
 - d. That cow's milk-based infant products are safe for preterm infants;
 - e. That cow's milk-based infant products are necessary for optimum growth;
 - f. That cow's milk-based infant products are similar or equivalent to breast milk;
 - g. That Enfamil was safe and more like breast milk than other infant products; and/or
 - h. That its products were based on up-to-date science, which made them safe for preterm infants.
- 73. Mead knew or reasonably should have known and/or determined that the above-referenced statements were false.
- 74. Those misrepresentations were intended to and did in fact induce hospitals and health care providers, including Baby Isabella's hospital and health care providers, to provide Enfamil to babies, including Baby Isabella.
- 75. Those misrepresentations were intended to and did in fact induce hospitals and health care providers, including Baby Isabella's hospital and health care providers, to provide their cow's milk-based products to babies, including Baby Isabella.

- 76. Mead's misrepresentations induced Baby Isabella's mother to allow her child to be fed Enfamil, in reliance on all the messaging she received about formula feeding, including Mead's messaging.
- 77. Had Mead not committed these negligent misrepresentations, Baby Isabella would not have been exposed to its unreasonably dangerous cow's milk-based products.
- 78. The aforesaid negligent acts and/or omissions of Mead proximately caused Baby Isabella's NEC which led to her death on November 1, 2013.
- 79. As a direct and proximate result of the aforesaid negligent acts and/or omissions, Mead proximately caused Baby Isabella's next of kin to suffer damages, including but not limited to, loss of money, benefits, goods, services, society, grief, sorrow, and mental suffering resulting from her death.
- 80. This count is brought pursuant to the Illinois Survival Act, 755 ILCS 5/27-6, the Illinois Family Expense Act, 750 ILCS 65/15, and the Illinois Wrongful Death Act, 740 ILCS 180/1.

WHEREFORE, Abigail Grosshuesch, Individually, and as Next Friend and Administrator of the Estate of Isabella Zormelo, Deceased, demands judgment against Mead Johnson & Co., LLC & Mead Johnson Nutrition Company, LLC, for a sum in excess of the jurisdictional limits of the Circuit Court of Madison County, Illinois.

COUNT X: NEGLIGENT MISREPRESENTATION – LOSS OF CONSORTIUM Abigail Grosshuesch v. Mead Johnson & Co., LLC & Mead Johnson Nutrition Co.

- 81. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
 - 82. At all times relevant herein, Abigail Grosshuesch was Isabella Zormelo's mother.

83. Abigail Grosshuesch, as Isabella Zormelo's mother, has suffered injuries including, but not limited to, loss of consortium.

WHEREFORE, Abigail Grosshuesch, Individually, demands judgment against Mead Johnson & Co., LLC & Mead Johnson Nutrition Company, LLC for a sum in excess of the jurisdictional limits of the Circuit Court of Madison County, Illinois.

COUNT XI: CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT

- 84. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.
- 85. Pursuant to the Illinois Consumer Fraud and Deceptive Business Practices Act, ILCS Ch. 815, Act 505, Mead engaged in deceptive acts or practices in the marketing and sale of their infant products.
- 86. Specifically, upon information and belief, Mead engaged in deceptive acts or practices, by making the following false statements of material fact on an ongoing and repeated basis and prior to the time Baby Isabella was fed its products:
 - a. That its cow's milk-based products were safe and beneficial for preterm infants;
 - b. That its cow's milk-based products were necessary to the growth and nutrition of preterm infants;
 - c. That its products have no serious side effects;
 - d. That cow's milk-based products were safe for preterm infants;
 - e. That cow's milk-based products were necessary for optimum growth;
 - f. That cow's milk-based products were similar or equivalent to breast milk;
 - g. That Enfamil was safe and more like breast milk than other infant products; and/or

- h. That its products were based on up-to-date science, which made them safe for preterm infants.
- 87. Mead further engaged in deceptive acts or practices, by omitting the material fact that their products significantly increased the risk of NEC, devastating injuries, and/or death in premature infants.
- 88. Mead's deceptive practices were intended to and did in fact induce hospitals and health care providers, including Baby Isabella's hospital and health care providers, to provide Enfamil to babies, including Baby Isabella.
- 89. Mead's deceptive practices were intended to and did in fact induce Abigail Grosshuesch to allow Baby Isabella to be fed Mead's Enfamil Acidified Liquid Human Milk Fortifier, in reliance on all the messaging she received about formula feeding, including, directly or indirectly, Mead's messaging.
- 90. Had Mead not committed these deceptive practices, Baby Isabella would not have been exposed to Mead's unreasonably dangerous cow's milk-based product, Enfamil Acidified Liquid Human Milk Fortifier.
- 91. The aforesaid negligent acts and/or omissions of Mead proximately caused Baby Isabella's NEC which caused her death on November 1, 2013.
- 92. As a direct and proximate result of the aforesaid negligent acts and/or omissions, Mead proximately caused Baby Isabella's next of kin to suffer damages, including but not limited to, loss of money, benefits, goods, services, society, grief, sorrow, and mental suffering resulting from her death.
- 93. This count is brought pursuant to the Illinois Survival Act, 755 ILCS 5/27-6, the Illinois Family Expense Act, 750 ILCS 65/15, and the Illinois Wrongful Death Act, 740 ILCS 180/1.

WHEREFORE, Abigail Grosshuesch, Individually, and as Next Friend and Administrator of the Estate of Isabella Zormelo, Deceased, demands judgment against Mead Johnson & Co., LLC & Mead Johnson Nutrition Company, LLC, for a sum in excess of the jurisdictional limits of the Circuit Court of Madison County, Illinois.

COUNT XII: CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT LOSS OF CONSORTIUM

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- 94. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.
 - 95. At all times relevant herein, Abigail Grosshuesch was Isabella Zormelo's mother.
- 96. Abigail Grosshuesch, as Isabella Zormelo's mother, has suffered injuries including, but not limited to, loss of consortium.

WHEREFORE, Abigail Grosshuesch, Individually, demands judgment against Mead Johnson & Co., LLC & Mead Johnson Nutrition Company, LLC for a sum in excess of the jurisdictional limits of the Circuit Court of Madison County, Illinois.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

- 97. For compensatory damages in an amount to be proven at trial;
- 98. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, loss of consortium, and other non-economic losses sustained as a result of Mead's conduct;
- 99. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

- 100. For interest as permitted by law, both prejudgment and post-judgment;
- 101. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
- For all other damages allowed by law and such other and further relief as the Court 102. deems proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial for all claims triable.

Dated: October 18, 2021 Respectfully submitted, ABIGAIL GROSSHUESCH, Individually, and as Next Friend and Administrator of the Estate of ISABELLA ZORMELO, Deceased

By her attorneys,

<u>|s| Elizabeth A. Kaveny</u>

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